Remarks

Claims 25 and 30-39 are pending in the subject application. By this Amendment, Applicants have amended claim 25 and added new claims 40-55. Amended claim 25 recites a method for suppression or inhibition of allergen-specific IgE production. Support for the amendments and new claims can be found throughout the subject specification including, for example, at page 5, lines 20-28; page 6, lines 18-26; page 7, lines 20-21; page 16, lines 9-29; page 17, lines 1-4 and 25-28; and page 18, lines 1-5, and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 25 and 30-55 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants gratefully acknowledge the Examiner's withdrawal of the finality of the previous Office Action dated May 19, 2003 and the withdrawal of the rejection of under 35 USC §103.

Claims 25 and 33-39 are rejected under 35 USC §§102(a) and (e) as being anticipated by Soos *et al.* (U.S. Patent No. 5,906,816). In addition, claims 25, 30-37, and 39 are rejected under 35 USC §§102(a) and (e) as being anticipated by Johnson *et al.* (U.S. Patent No. 5,939,286). The Examiner asserts that the Soos *et al.* patent teaches mammalian interferon tau and that it is useful for the treatment of autoimmune disease and that the Johnson *et al.* patent teaches interferon tau/interferon alpha chimeras and treatment of immune system disorders, including allergy, using the chimeras. Applicants respectfully traverse these grounds of rejection.

Applicants respectfully assert that the cited patents do not anticipate the claimed invention. In making these rejections, the Examiner asserts that the use of interferon tau to treat autoimmune disorders or allergy would "inherently result in suppression of IgE production." It is well established that a new use for a known composition of matter is patentable subject matter. Examples of where the Patent Office has granted "use" patents on known compounds include patents on the use of minoxidil to promote hair growth (see, for example, U.S. Patent Nos. 4,139,619 and 4,596,812). U.S. patents on minoxidil issued in the late 1960's and the drug was administered to patients to treat hypertension. It was subsequently observed that treatment of patients with minoxidil for hypertension also promoted hair growth on the patient's body. Thus, the property of minoxidil of promoting hair growth would have been considered "inherent" in the administration of minoxidil to patients under the Examiner's reason for rejection of Applicants' claimed invention, yet the U.S.

Patent Office granted "method of use" claims directed to the use of minoxidil to promote hair growth.

It is also well established in patent law that the presence of an inherent property or effect must be grounded on more than speculation, it must be a certainty and a person of ordinary skill in the art must necessarily recognize its presence. *Scaltech Inc. v. Retec/Tetra L.L.C.*, 48 USPQ2d 1037 (Fed. Cir. 1998), revised and reissued, 51 USPQ2d 1055, 1059 (Fed. Cir. 1999) ("Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient to establish inherency.") (emphasis added); *Crown Operations International Ltd. v. Solutia Inc.*, 62 USPQ2d 1917 (Fed. Cir. 2002). Applicants respectfully assert that at the time of the present invention it was not a certainty that the administration of interferon tau in treating autoimmune disorders or allergy would result in suppression of IgE production. In fact, the Examiner acknowledges this at page 2, section 2, of the instant Office Action wherein it is stated that "It is agreed that . . . one of ordinary skill . . . would not have known whether interferon τ would affect IgE levels." Thus, Applicants respectfully assert that the inhibition or suppression of IgE production or proliferation of IgE-producing cells by interferon tau was not "inherent" in the disclosure of treatment of patients with interferon tau in the cited patents.

It is generally acknowledged in the art that B lymphocyte production of antibodies (immunoglobulins) is a complex process. Firstly, there are five immunoglobulin heavy chains that determine the properties of an antibody molecule. These heavy chains determine what is known as the immunoglobulin (and antibody) isotype, of which IgE is but one type. Mature B cells constitutively express immunoglobulins of the IgM and IgD isotype on their surfaces. Antigen stimulation and T helper cell involvement directly, and via cytokines, result in clonal expansion of antigen-specific B cells. There is also the complex event of immunoglobulin gene rearrangement known as isotype switching. Normally, the IgE isotype that is associated with the allergies is not expressed at significant levels and, therefore, IgE serum levels tend to be low. For reasons that are not known, a fraction of individuals express high levels of IgE and this results in atopic (hayfever, *etc.*) and asthma-type allergies. The biochemical and molecular events and mechanisms associated with IgE-specific allergy are so complex that it was impossible at the time of the present invention to

predict that IgE-type allergies would be suppressed by interferon tau. This had to be determined empirically.

In addition, subsequent to the filing of U.S. provisional application No. 60/151,026, to which the subject application claims priority under 35 USC §119(e), Applicants submitted a manuscript disclosing the subject invention to the *Journal of Allergy and Clinical Immunology*, a peer reviewed journal. The manuscript was accepted and published in that journal in November 1999 (Mujtaba, M.G. *et al.*, "IFN-τ Inhibits IgE Production in a Murine Model of Allergy and in an IgE-Producing Human Myleoma Cell Line" *J Allergy Clin Immunol* 104(5):1037-1044). The published manuscript was cited in an Information Disclosure Statement dated February 20, 2001 in the subject application and a copy of the published manuscript provided therewith. Applicants respectfully assert that the acceptance and publication of their work in the *Journal of Allergy and Clinical Immunology* is evidence as to the novelty and nonobviousness of their discovery and the claimed invention. Peer-reviewed, scientific journals typically do not publish manuscripts detailing research results that are not new or that would be considered "obvious" by the scientific community. Prior to the Applicants' discovery, any suggestion that interferon tau inhibited IgE production or proliferation of IgE-producing cells would have been nothing more than mere speculation. That Applicants' discovery warranted publication in a well known, well respected, peer reviewed journal is clear evidence that the scientific community considered their discovery novel and nonobvious.

In view of the above remarks, reconsideration and withdrawal of the rejections under 35 USC §§102(a) and 102(e) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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